IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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February 2, 2017

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 1, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Alpha$_2$ Agonists, Extended-Release; Daclizumab (Zinbryta); and Naloxone Nasal Spray (Narcan Nasal Spray). Additionally, the DUR Commission members made a recommendation to remove the Buprenorphine Transdermal System & Buccal Film prior authorization criteria and move the medications to the Long-Acting Opioids prior authorization criteria. Finally, the DUR Commission members made a recommendation to implement a ProDUR age edit on codeine containing agents. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments that were received from the medical/pharmacy associations in response to a December 14, 2016 letter that was sent to them detailing the proposed criteria for Alpha$_2$ Agonists, Extended-Release; Daclizumab (Zinbryta); Naloxone Nasal Spray (Narcan Nasal Spray); the removal of the Buprenorphine Transdermal System & Buccal Film prior authorization with the medications being moved to the Long-Acting Opioids prior authorization criteria; as well as the proposed ProDUR age edit on codeine containing agents.

Alpha$_2$ Agonists, Extended-Release

Proposed Clinical Prior Authorization Criteria (changes noted)
Prior authorization is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:

1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and
2. Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and

3. Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant.~~; and~~
~~4. Previous trial and therapy failure at a therapeutic dose with atomoxetine (Strattera®).~~

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Daclizumab (Zinbryta)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for daclizumab (Zinbryta). Payment will be considered under the following conditions:

1. Patient has a diagnosis of a relapsing form of multiple sclerosis (MS); and
2. Patient is 18 years of age or older; and
3. Patient has documentation of previous trials and therapy failures with two or more drugs indicated for the treatment of MS; and
4. Patient does not have pre-existing hepatic disease or hepatic impairment (including hepatitis B or C); and
5. Baseline transaminases (ALT, AST) and bilirubin levels are obtained; and
6. Patient does not have an ALT or AST at least 2 times the upper limit of normal (ULN); and
7. Patient does not have a history of autoimmune hepatitis or other autoimmune condition involving the liver, and
8. Patient has been screened for TB and treated for TB if positive; and
9. Daclizumab will be used as monotherapy; and
10. Daclizumab will be dosed as 150 mg once monthly; and
11. Prescriber, patient, and pharmacy are enrolled in the Zinbryta REMS program.
12. The 72-hour emergency supply rule does not apply to daclizumab.
13. Lost or stolen medication replacement requests will not be authorized.

If criteria for coverage are met, an initial authorization will be given for 12 months. Additional authorizations will be considered when documentation of a positive clinical response to daclizumab therapy is provided.

Narcan (Naloxone) Nasal Spray

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for a patient requiring more than 2 doses of Narcan (naloxone) nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. Documentation is provided indicating why patient needs additional doses of Narcan (naloxone) nasal spray (accidental overdose, intentional overdose, other reason); and
2. Narcan (naloxone) nasal spray is to be used solely for the patient it is prescribed for; and
3. The patient is receiving an opioid as verified in pharmacy claims; and
4. Patient has been reeducated on opioid overdose prevention; and

5. Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and
6. A treatment plan is included documenting a plan to lower the opioid dose.

Buprenorphine Transdermal System & Buccal Film - Removal of current criteria and subject medications to the Long-Acting Opioids criteria

Current Clinical Prior Authorization Criteria for Buprenorphine Transdermal System & Buccal Film *(to be removed)*

~~Prior authorization is required for Butrans and Belbuca. Payment will be considered when the following conditions are met:~~

1. ~~Previous trials and therapy failures at a therapeutic dose with two long acting opioids. The preferred trials must allow for adequate dose titration and show use of a short acting narcotic for breakthrough pain.~~
2. ~~A trial and therapy failure with fentanyl patch at maximum tolerated dose.~~

~~The required trials may be overridden when documented evidence it provided that use of these agents would be medically contraindicated.~~

Current Clinical Prior Authorization Criteria for Long-Acting Opioids *(buprenorphine transdermal system & buccal film would be subject to criteria below and going forward as updates are made by the DUR Commission)*

Prior authorization is required for all non-preferred long-acting opioids. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and
2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
4. There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and
5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and
6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and
7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.

8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered.

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a long-acting opioid is appropriate for this member.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Additionally, the DUR Commission made a recommendation to implement a ProDUR age edit on codeine containing products, restricting its use in children under 18 years of age and removing the 72-hour emergency supply allowance for this age group.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Alpha$_2$ Agonists, Extended-Release; Daclizumab (Zinbryta); Naloxone Nasal Spray (Narcan Nasal Spray), removal of Buprenorphine Transdermal System & Buccal Film prior authorization with the medications subject to the already established Long-Acting Opioids prior authorization criteria, and the ProDUR age edit on codeine containing agents.

Sincerely,

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Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME